

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

VEIN & WELLNESS GROUP, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:22-cv-00397-JMC
	)	
XAVIER BECERRA, in his capacity as	)	
Secretary of the United States Department	)	
of Health and Human Services,	)	
	)	
Defendant.	)	

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**DEFENDANT’S REPLY IN FURTHER SUPPORT OF ITS MOTION  
FOR SUMMARY JUDGMENT AND IN OPPOSITION TO  
PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

**I. Introduction.**

It is *undisputed* that the final administrative decision under review is legally correct and supported by substantial evidence. Defendant, Xavier Becerra, Secretary of the U.S. Department of Health and Human Services (“the Secretary”) moved for summary judgment, establishing that the final administrative decision under review should be upheld because it is both legally correct and supported by substantial evidence. ECF No. 18. In its June 27, 2022 filing opposing the Secretary’s motion and cross-moving for summary judgment, Plaintiff, Vein & Wellness Group, LLC (“Vein & Wellness”), raised no *substantive* challenge to the Secretary’s position.<sup>1</sup> *See*

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<sup>1</sup> Although Vein & Wellness asserts it has substantive evidence in support of its position that the services at issue are medically necessary that it did not submit, this Court’s review is limited to the administrative record. 42 U.S.C. § 405(g) (judicial review of the Secretary’s final administrative decision is limited to considering the administrative record); 42 U.S.C. § 1395ff(b)(3) (healthcare providers “may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the [QIC] . . . unless there is good cause); *see also Cumberland County Hosp. System, Inc. v. Burwell*, 816 F.3d 48, 55-56 (4th Cir. 2016) (for evidence to be considered in the Medicare claim appeals process, providers must submit evidence in the Reconsideration process or earlier). Therefore, Vein & Wellness is statutorily prohibited from presenting any new information in support of its position.

*generally* Plaintiff's Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment and in Support of Plaintiff's Cross-Motion for Summary Judgment, ECF No. 24-1 ("Pl.'s Mem. Summ. J."). Therefore, the final administrative decision under review should be affirmed.

Ignoring the substance of the final decision, Vein & Wellness moves for summary judgment and opposes the Secretary's motion exclusively based on the following defenses: (1) the final administrative decision denied Medicare coverage based on an allegedly "new issue" – lack of medical necessity – thereby violating agency regulations which limit the scope of administrative appeals; and (2) the Secretary is allegedly collaterally estopped from denying coverage for the MOCA procedure in the instant case because several earlier ALJ decisions granted Vein & Wellness Medicare coverage for the MOCA procedure.

As explained more fully below, Vein & Wellness's arguments have no merit. First, the Secretary's final administrative decision did not violate agency regulations limiting the scope of the administrative appeal. Congress authorizes Medicare coverage only for items and services that are medically reasonable and necessary (42 U.S.C. § 1395(a)(1)(A)). Therefore, the law prohibits Medicare coverage of items and services that are not medically reasonable and necessary regardless of whether the issue is raised during an interim administrative proceeding. Additionally, all three of the lower-level administrative decisions issued prior to the ALJ decision denied the claims for lack of medical necessity and, therefore, it was not a "new issue." *See* Memorandum of Law in Support of Defendant's Motion for Summary Judgment, ECF No. 18-1 at 12-14 ("Def.'s Mem. Summ. J.").<sup>2</sup>

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<sup>2</sup> The referenced page numbers herein correspond to the electronically-stamped pagination across the top of the case filings, not the page numbering in the footer of each page.

Second, the Secretary is not collaterally estopped from denying the claims here. Collateral estoppel is inapplicable to the Medicare claim appeals process. Federal regulations provide that ALJ decisions do not bind the Secretary in future cases. 42 C.F.R. § 401.109 (only Medicare Appeals Council decisions have the potential to become precedential). Additionally, applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute. *Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (elevating nonprecedential administrative appeals decisions into binding coverage rules would “stultify the administrative process”). Moreover, applying collateral estoppel in this context would violate the Appropriations Clause of the U.S. Constitution, Ar. I, § 9, cl.7. Finally, Vein & Wellness has failed to establish the elements of the defense. *Eddy v. Waffle House, Inc.*, 482 F.3d 674, 679 (4th Cir. 2007) (identifying five elements for collateral estoppel).

The Secretary’s position is undisputed that the final administrative decision is legally correct and supported by substantial evidence. Neither of Vein & Wellness’s defenses has any merit. Accordingly, the final administrative decision under review should be affirmed.

## **II. The Secretary’s Denial of Medicare Coverage Based on Lack of Medical Necessity Did Not Violate Agency Regulations.**

Vein & Wellness asserts the Secretary’s final administrative decision allegedly violated agency regulations because it impermissibly addressed the issue of whether the services were medically reasonable and necessary under the Medicare program. Pl.’s Mem. Summ. J. at 17-19.<sup>3</sup> Specifically, Vein & Wellness contends the regulations limited the Medicare Appeals

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<sup>3</sup> Vein & Wellness further contends that these alleged regulatory violations constitute Administrative Procedure Act violations. Vein & Wellness specifically alleges the supposed regulatory violations simultaneously constitute violations of 5 U.S.C. §§ 706(2)(A) (not in accordance with the law) and 706(2)(D) (without observance of procedure required by law). Pl.’s Mem. Summ. J. at 19.

Council to consider only the issues raised in the administrative proceeding below (*i.e.*, the ALJ proceeding). *Id.* According to Vein & Wellness, because the ALJ proceedings did not consider the issue of medical necessity, the regulations prohibited the Medicare Appeals Council from considering this issue of which Vein & Wellness had no notice. *Id.* This argument is both legally and factually incorrect.

Vein & Wellness's assertion that the Secretary's final administrative decision violated agency regulations is incorrect as a matter of law. The plain language of the applicable regulations reveals the Medicare Appeals Council was *not* limited to addressing exclusively the issues raised before the ALJ. The regulation at 42 C.F.R. § 405.1110(c)(2) provides that, when CMS refers an ALJ decision for review, the Medicare Appeals Council applies the following standard of review:

The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

*Id.* In the instant case, the Medicare Appeals Council appropriately considered the exceptions CMS raised in its referral. *Compare* CAR 23-163 (CMS Referral for Own Motion Review), *with* CAR 11-22 (Medicare Appeals Council decision). Moreover, the regulations make clear that, when the Medicare Appeals Council engages in review of an ALJ decision, it conducts a *de novo* review. 42 C.F.R. §§ 405.1100, 405.1108(a).

Deliberately avoiding any mention of the applicable regulations governing *Medicare Appeals Council* review, Vein & Wellness instead inappropriately focuses on the regulations governing *ALJ* review. Indeed, Vein & Wellness incorrectly claims the *Medicare Appeals Council* decision violated two regulations governing *ALJ* review 42 C.F.R. §§ 405.1032 (Issues

before an ALJ) and 405.1018 (Submitting evidence in an administrative proceeding). *See* Pl.’s Mem. Summ. J. at 17. However, the regulations Vein & Wellness cite do not apply to Medicare Appeals Council proceedings. *Compare* 42 C.F.R. §§ 405.1000-405.1063 (Regulations governing ALJ proceedings), *with* 42 C.F.R. §§ 405.1100-405.1140 (Regulations governing Medicare Appeals Council proceedings).

Moreover, even if *arguendo* Vein & Wellness were correct (which it is not) that the regulations governing *ALJ proceedings* restricted the Medicare Appeals Council to address only the issues raised in the ALJ hearing, the regulations governing *Medicare Appeals Council proceedings* explicitly authorize the Council to correct errors of law. 42 C.F.R. § 405.1110(c)(2). Relevant to this case, Congress authorizes Medicare coverage only for items and services that are medically reasonable and necessary (42 U.S.C. § 1395(a)(1)(A)). Therefore, the Medicare Appeals Council was authorized to correct the ALJ’s legal error in determining the MOCA procedures were covered under the Medicare program because, at the time the services were provided, they were not medically reasonable and necessary. Def.’s Mem. Summ. J. at 23-26.

Additionally, Vein & Wellness’s claim that it was never provided with notice that the claims for MOCA procedures were denied based on a lack of medical necessity is factually incorrect. Pl.’s Mem. Summ. J. at 17. As Defendant identified in more detail in its Memorandum of Law in Support of its Motion for Summary Judgment, all three of the lower-level administrative decisions issued prior to the ALJ decision denied the claims for lack of medical necessity and, therefore, it was not a “new issue.” Def.’s Mem. Summ. J. ¶¶ 9-14.<sup>4</sup> Not

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<sup>4</sup> The Secretary’s brief describes these administrative appeal decisions in more detail. The Initial Determination denied the claims at issue based on lack of medical necessity. Def.’s Mem. Summ. J. ¶ 9-11. Although the Redetermination (¶ 13) and Reconsideration (¶ 14) decisions also

only did Vein & Wellness have notice that the original claim denials were based on lack of medical necessity, but it also was *required* to submit any evidence it intended to present in support of its challenge to those claim denials based on lack of medical necessity along with its Redetermination and Reconsideration requests. *See* 42 C.F.R. § 405.946 (requiring the party requesting Redetermination to “explain why it disagrees with the contractor’s determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination”); 42 C.F.R. § 405.966 (“When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.”) Thus, Vein & Wellness’s claim that it purportedly did not have notice or an opportunity to respond to the fact that the Medicare claims were being denied due to lack of medical necessity is belied by the record.

In sum, Vein & Wellness has failed to establish that the Secretary violated any regulations including 42 C.F.R. §§ 405.1032 or 405.1018 by denying the Medicare claims at issue based on a lack of medical necessity. Nor has Vein & Wellness established any other kind of procedural defect under the Administrative Procedure Act, 5 U.S.C. §§ 706(2)(A) or 706(2)(D), because its assertion that it had no notice the claims were improper because they lacked medical necessity is false.

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incorrectly identified an inapplicable local coverage determination and the Reconsideration decisions noted a problem with incorrect coding, both the Redetermination and Reconsideration decisions were nevertheless fundamentally based on a lack of medical necessity. *See, e.g.,* Def.’s Mem. Summ. J. ¶ 13 (Redetermination upholding the claims denials for the MOCA procedures because “the information provided did not support the need for this service or item”); *See, e.g.,* Def.’s Mem. Summ. J. ¶ 14 (Reconsideration upholding the claims denials for the MOCA procedures because the services “did not meet the requirements to be considered reasonable and necessary in the treatment of the patients”).

### **III. Vein & Wellness's Collateral Estoppel Argument Has No Merit.**

Vein & Wellness has presented three administrative decisions issued by one ALJ which granted Vein & Wellness Medicare coverage for the procedure based on other claims submissions that are not the subject of the instant case. *See* Pl.'s Mem. Summ. J. at Exs. A, B, C. Vein & Wellness asks this Court to estop the Secretary from denying Medicare coverage for MOCA procedures in the instant case based on three prior erroneous,<sup>5</sup> non-precedential administrative decisions. However, the Secretary is not collaterally estopped from denying the claims at issue here.

#### **A. Collateral Estoppel is Inapplicable to Medicare Claim Appeals.**

The only court that has squarely addressed the issue of whether administrative decisions regarding Medicare coverage determinations can be used to collaterally estop the federal government in subsequent determinations has definitively concluded that they cannot. *Prosser v. Azar*, No. 20-C-194, 2020 WL 3642315, at \*5 (E.D. Wisc. July 6, 2020) *aff'd on other grounds*, *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021). In *Prosser*, plaintiff beneficiary sought review of ALJ decisions denying coverage for Tumor Treatment Field Therapy (TTFT). *Id.*, at \*1. The Medicare Administrative Contractors had issued a Local Coverage Decision (LCD) denying coverage because the scientific evidence at the time did not then support TTFT as a medically reasonable and necessary service under the Medicare program. *Id.* Several ALJs denied Medicare coverage based on the LCD; however, some other ALJs ignored the LCD and granted Medicare coverage in several other prior administrative decisions. *Id.* Plaintiff beneficiary sought to collaterally estop the Secretary from denying Medicare coverage in that case, arguing

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<sup>5</sup> The three ALJ decisions Vein & Wellness asserts should operate to collaterally estop the government from denying Medicare coverage here are incorrect as a matter of law for the reasons explained in the Medicare Appeals Council Decision at CAR 11-22.

the Secretary was bound by the previous ALJ decisions which had erroneously granted coverage.

*Id.* The district court rejected plaintiff's argument, holding collateral estoppel did not apply in this context:

These Medicare regulations reveal an administrative review structure incompatible with applying collateral estoppel at the agency level. To begin, Plaintiffs have not shown that ALJ decisions are "final judgments" as understood for purposes of collateral estoppel, particularly in light of the Secretary's view that his regulations vest the sole authority to deem a [Medicare Appeals] Council decision precedential with the chair of the appeals board.

*Id.*, at \*5. The district court also found there was no finality to the ALJ decisions at issue in that case because the Secretary was not "fully heard" in those proceedings where he did not participate. *Id.*, at \*7. The district court further concluded it is "administratively impossible for the Secretary to represent himself at every ALJ hearing" and, therefore, "it would be unreasonable to apply estoppel by default across multiple claims." *Id.*

Vein & Wellness relies on the Supreme Court's decision in *Astoria* to press its argument that the favorable ALJ decisions should have preclusive effect, but they omit that the Court held the agency decision in question had no preclusive effect. Pl.'s Mem. Summ. J. at 19; *Astoria*, 501 U.S. at 106. In *Astoria*, the Court explained that agency decisions should not be given preclusive effect when there is a statute expressing a contrary intent on the issue of preclusion. 501 U.S. at 108; *see also Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (stating that collateral estoppel cannot be applied if it would "frustrate congressional intent or impede the effective functioning of the agency"). At issue in *Astoria* was whether, under the Age Discrimination in Employment Act, "the judicially unreviewed findings of a state administrative agency decision" precluded re-litigation in federal court. 501 U.S. at 106. The Court noted that the statute required plaintiffs to pursue their claims under state law first and that state administrative proceedings had to be concluded before bringing suit in federal court. *Id.* at

111. Therefore, the Court concluded it was safe to assume “the possibility of federal consideration after state agencies have finished theirs.” *Id.* If the state agency decision was given preclusive effect, the “federal proceedings would be strictly *pro forma*.” *Id.*

Vein & Wellness relies on several other cases for the assertion that collateral estoppel should apply to unreviewed ALJ decisions which make Medicare benefit and coverage determinations, but they are inapposite. Pl.’s Mem. Summ. J. at 9-11. The only case concerning Medicare is not on point because it concerns a district court’s review of a request for declaratory and injunctive relief, not a coverage determination on the merits. *See DeWall Enter. Inc. v. Thompson*, 206 F. Supp. 2d 992 (D. Neb. 2002) (granting mandamus jurisdiction and preliminary injunction in favor of durable medical equipment supplier).

The other decisions Vein & Wellness cites concerning administrative decisions outside the Medicare context are similarly misplaced.<sup>6</sup> *B & B Hardware, Inc. v. Hargis Indus.* involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. 575 U.S. 138 (2015). *Continental Can Co. v. Marshall* was decided well before *Astoria*, and therefore fails to perform the required analysis of whether there was a statute prohibiting collateral estoppel. 603 F.2d 590 (7th Cir. 1979); *see B & B Hardware*, 575 U.S. at 148 (applying *Astoria*’s rule that issue preclusion cannot be applied if there is a statute preventing it). *Bowen v. United States* was decided pursuant to Indiana’s collateral estoppel law and, in contrast to the statutes in this case, Indiana law specifically stated that a federal administrative agency decision finding violations of air safety rules also constituted a state law

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<sup>6</sup> The district court in *Prosser* dismissed as inapposite cases plaintiffs had cited regarding decisions applying collateral estoppel to administrative decisions outside the Medicare context. 2020 WL 3642315, at \*7 (“Solely because [collateral estoppel] applies in some administrative contexts, however, does not mean it applies elsewhere. Medicare’s labyrinth review system and myriad regulations suggest an administrative scheme unlike others.”).

violation because the state law incorporated the federal standard. In effect, the statute required collateral estoppel rather than prohibiting it. 570 F.2d 1311, 1319-20 (7th Cir. 1978). The court in *C & N Corp. v. Kane*, like *B & B Hardware*, did not consider whether the federal government may be bound by administrative decisions; it considered only whether private parties could be bound. 953 F. Supp. 2d 903 (E.D. Wisc. 2013). Finally, the Supreme Court later explicitly held in *B & B Hardware* that the type of administrative decision at issue in *C & N Corp.* could be preclusive only because the Lanham Act did not prohibit it. *See* 575 U.S. 138.

1. *Federal regulations provide that ALJ decisions do not bind the Secretary in future cases.*

The Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions. In fact, the Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of nonprecedential decisions that are not binding. In Medicare coverage cases, only Medicare Appeals Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given “precedential effect” and is binding on “all [U.S. Department of Health and Human Services] components that adjudicate matters under the jurisdiction of CMS.” *Id.* § 401.109(c). The term “precedential effect” means that the Medicare Appeals Council’s:

- (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
- (2) Factual findings are binding and must be applied to future

determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

*Id.* § 401.109(d). Accordingly, the term “precedential effect” is synonymous with a decision having binding or preclusive effect. It is undisputed that no Medicare Appeals Council decision, much less one designated as precedential, have favorably decided Vein & Wellness’s claims.

The regulations make clear that only “[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . .” 42 C.F.R. § 405.1063(c). Indeed, ALJ decisions are not even binding on lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Medicare Appeals Council must “review the case *de novo*.” 42 U.S.C. § 1395ff(d)(2)(B); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) (“Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.”) (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Medicare Appeals Council from denying Medicare coverage for the same services, the Medicare Appeals Council could not perform a *de novo* review; instead, the Medicare Appeals Council would be bound to accept the ALJ’s conclusions.

In *Almy v. Sebelius*, the Fourth Circuit concluded that the Medicare Appeals Council’s obligation to undertake *de novo* review was “incompatible with [plaintiff’s] proffered notion that the [Medicare Appeals Council] is somehow obligated to defer to the outcomes of prior decisions below.” 679 F.3d 297, 310 (4th Cir. 2012). The Fourth Circuit further explained:

[T]he decisions of local contractors cannot deprive [the Secretary] of discretion [to make final determinations], any more than the diverse decision of district courts or courts of appeals throughout the country could bind the Supreme Court. It was therefore not arbitrary and capricious of the [Medicare Appeals Council] to make final determinations that may have been at odds with prior coverage decisions that did not carry the full imprimatur of the Secretary's authority.

679 F.3d at 311 (footnote omitted).

The Restatement (Second) of Judgments § 83, Paragraph 4 (1982)<sup>7</sup> is in accord:

An adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that:

- (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings; or
- (b) The tribunal in which the issue subsequently arises to be free to make an independent determination of the issue in question.

Medicare regulations clearly state ALJ decisions are not to be accorded conclusive effect as they are non-precedential, and the Medicare Appeals Council's *de novo* review means it is free to make an independent determination. Accordingly, the Medicare statutes and regulations bar the application of collateral estoppel based on the ALJ decisions Vein & Wellness has presented to this Court.

2. *Applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute.*

If ALJ decisions were to be deemed binding, it would run contrary to the deference and discretion afforded to the Secretary to implement the Medicare statute, particularly regarding the “reasonable and necessary” standard for coverage of items and services furnished to program

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<sup>7</sup> The Supreme Court has noted it “regularly turns” to this Restatement for guidance on issue preclusion. *B & B Hardware*, 575 U.S. at 148.

beneficiaries. *Wilkins v. Sullivan*, 889 F.2d 135, 140 (7th Cir. 1989) (in discussing review of denial of Medicare benefits, the court opined “[i]t is precisely this type of decision—made within the context of an extremely technical and complex field—that courts should leave in the hands of expert administrators . . . . Congress delegated these difficult decisions to agencies that have developed specialized knowledge”).

“[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.” *Almy*, 679 F.3d at 303 (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). The Medicare statute and regulations preserve “this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing a [National Coverage Determination], by allowing regional contractors to adopt a [Local Coverage Determination], or by deciding individual cases through the adjudicative process.” *Id.* The Supreme Court has foreclosed arguments that interfere with this discretion, holding that “[t]he Secretary’s decision as to whether a particular medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also Shalala v. Guernsey Mem’l Hosp.*, 514 U.S. 87, 97 (1995) (“The Secretary’s mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.”).<sup>8</sup>

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<sup>8</sup> As explained more fully in the Memorandum of Law in Support of Defendant’s Motion for Summary Judgment, to administer the “reasonable and necessary” standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that “either by default rule or by specification, address every conceivable question” that may arise. *Guernsey Mem’l Hosp.*, 514 U.S. at 96.

As explained above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare providers and beneficiaries, who, even after repeated denials of similar claims have the right to *de novo* review of any subsequent claims. The application of collateral estoppel would be fundamentally inconsistent with individual adjudication of Part B claims. In Vein & Wellness’s view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary.<sup>9</sup> Accordingly, it is within the Secretary’s discretion *not* to be bound by ALJ rulings. *See Ringer*, 466 U.S. at 607-608 (distinguishing between ALJ and Medicare Appeals Council-level decisions that “applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases” and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

While Vein & Wellness fails to cite any cases on point,<sup>10</sup> this Circuit rejected a similar attempt to bind federal agencies to non-precedential decisions in lower-level administrative

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<sup>9</sup> As Vein & Wellness notes, the three favorable ALJ decisions that granted Medicare coverage for the MOCA procedure were issued on July 21, 2021, September 14, 2021, and September 30, 2021, respectively. *See* Declaration of J. Pistorino in Support of Cross Motion for Summary Judgment and Opposition to Defendant’s Motion for Summary Judgment, ECF No. 24-2 at 1. The Medicare Appeals Council decision denying Medicare coverage for the MOCA procedure was issued on December 14, 2021 *after the three favorable ALJ decisions*.

<sup>10</sup> Vein & Wellness cites to a case concerning the unique circumstances of immigration appeals. *Islam v. Dept. of Homeland Sec.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, unlike the Medicare statute and regulations’ prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*.

appeals.<sup>11</sup> In *Almy*, plaintiff asserted that Medicare Appeals Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that “[t]he Secretary’s own regulations make clear that any policy implications in an adjudication do not have precedential effect . . . The purported ‘policy’ in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage.” *Id.* at 303 (citing 42 C.F.R. § 405.1062). The court noted that Congress gave the Secretary discretion to “decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year.” *Id.* at 304. Additionally, the Court further noted that other circuits have concluded that “[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently.” *Id.* at 310 (quoting *Community Case Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Just as in *Almy*, this Court should similarly reject Vein & Wellness’s attempt to elevate

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<sup>11</sup> Other Circuits have rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. *See, e.g., Int’l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (explicitly adopted the reasoning in *Almy*, reversing a district court decision that “incorrectly measured agency inconsistency across” ALJ decisions); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (“[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.”); *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (case citations omitted) (emphasizing the court’s “well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions”); *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008) (holding that “a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency”); *Abraham Mem’l Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) (“The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS’s long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative.”).

nonprecedential ALJ opinions into binding coverage rules, which would “stultify the administrative process.” *Id.* (quoting *Chenery*, 332 U.S. at 202).

In sum, “Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, any more than the diverse decisions of district court or courts of appeals throughout the country could bind the Supreme Court.” *Almy*, 679 F.3d at 311. The doctrine of collateral estoppel cannot transform an ALJ ruling from what it is – a decision by an intermediate-level tribunal that is only binding in a single case – to what it is not, an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral estoppel is contrary to the Appropriations Clause of the U. S. Constitution.*

The Appropriations Clause of the Constitution, Art. I, § 9, cl. 7, provides that: “No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law.” In *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414 (1990), the Supreme Court held that the government was not equitably estopped from making a determination to deny disability benefits for a claimant based on a federal employee’s oral and written representations. The Supreme Court concluded:

Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel, for courts cannot estop the Constitution.

*Id.* at 434.

Courts have applied the holding in *Richmond* to the Medicare context. In *Monongahela Valley Hosp. v. Sullivan*, 945 F.2d 576 (3d Cir. 1991), the court held that *Richmond* foreclosed a

Medicare provider's estoppel claim against the Secretary for additional Medicare reimbursement. *Id.* at 588-89. Likewise, in *Downtown Med. Ctr./Comprehensive Health Care Clinic v. Bowen*, the Tenth Circuit declined to estop the Secretary and a private insurer, which processed Medicare claims on the Secretary's behalf, from denying the plaintiff's reimbursement claim. 944 F.2d 756, 771 (10th Cir. 1991); *see also Almy*, 679 F.3d at 312 ("It is the Secretary, not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system.").

The same reasoning applies to Vein & Wellness's assertion of collateral estoppel. Vein & Wellness seeks to estop the Secretary from denying their claims payment from the Medicare Trust Fund. Of course, no appropriation of Congress entitles Vein & Wellness to future payments from the Medicare Trust Fund. Because Vein & Wellness seeks to draw money from the Treasury on equitable grounds, the Court must deny their assertion of collateral estoppel.

**B. Vein & Wellness Has Failed to Establish the Elements of Collateral Estoppel.**

Even if collateral estoppel could be invoked in this case, the elements have not been met.

The party invoking collateral estoppel has the burden to show:

- (1) The issue sought to be precluded is identical to one previously litigated;
- (2) The issue must have been actually determined in the prior proceeding;
- (3) Determination of the issue was a critical and necessary part of the decision in the prior proceeding;
- (4) The prior judgment must be final and valid; and
- (5) The party against whom estoppel is asserted must have had a full and fair opportunity to litigate the issue in the previous forum.

*Eddy v. Waffle House, Inc.*, 482 F.3d 674, 679 (4th Cir. 2007).<sup>12</sup> Vein & Wellness has not carried its burden on the first, second, and fifth elements.

1. *The issues are not the same.*

The issue Vein & Wellness seeks to preclude – the services at issue were not medically necessary – is not the same issue the ALJ addressed and decided in the three decisions Vein & Wellness now claims operate to bind the Secretary. The Secretary’s final administrative decision addressed the issue of whether the services at issue were medically reasonable and necessary under the Medicare program. CAR 14-22. The three ALJ decisions Vein & Wellness asserts operate to bind the Secretary did not address the issue of whether the services were medically reasonable and necessary under the Medicare program. *See* Pl.’s Mem. Summ. J. at Exs. A, B, C. The three ALJ decisions, all issued by the same ALJ, addressed only the following two issues: (1) Were the physician’s surgical services properly billed under code 37214 such that they were covered and payable on the date of services?; and (2) If the services are not covered, do the limitation of liability provisions under Section 1879 of the Act or any other law apply? If not, who is financially responsible? *Id.*

Accordingly, because the three ALJ decisions Vein & Wellness cites failed to address the

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<sup>12</sup> Plaintiff’s representations about the burden of proof are incorrect. Pl.’s Mem. Summ. J. at 9. Plaintiff asserts the party opposing collateral estoppel bears the burden of establishing that the presumption has been overcome; however, the opposite is true. Plaintiff cites to *Green v. Bock Laundry Mach. Co.* for the proposition that a party asserting that collateral estoppel does not apply bears the burden of establishing that the presumption has been overcome. But *Bock Laundry* does not address collateral estoppel nor a situation even anecdotally relevant for the Court’s analysis of whether to apply collateral estoppel in the instant action. Rather, the Supreme Court addressed whether Federal Rule of Evidence 609(a)(1) required a judge to let a civil litigant impeach an adversary’s credibility with evidence of the adversary’s prior felony convictions. *Id.* at 505. While it is true the Court interpreted legislation that arguably changed settled law, this proposition that Plaintiff cites to has little to do with collateral estoppel and which party carries the burden to demonstrate whether the doctrine should be applied.

issue of whether the services at issue were medically reasonable and necessary under the Medicare program, the three decisions cannot operate to estop the Secretary from denying the claims in the instant case for lack of medical necessity. *See, e.g., In re Duncan*, 448 F.3d 725, 730 (4th Cir. 2006) (holding that state wrongful death judgment did not collaterally estop litigation on issue of whether debtor caused the child's death by willful and malicious injury because Court could not determine whether the identical issue before it had previously been decided by state court); *Fullerton Aircraft Sales and Rentals, Inc. v. Beech Aircraft Corp.*, 842 F.2d 717, 720 (4th Cir. 1988) (holding that an airplane buyer was not collaterally estopped from maintaining breach of express and implied warranty claims against manufacturer by virtue of prior judgment because it determined only that asserted abnormality did not substantially impair airplane's value and rendered no determination on whether aircraft had defect that breached alleged warranties).

2. *The issue of medical necessity was not actually determined in the prior ALJ Decisions.*

As to the second element, the prior ALJ decisions did not actually determine the issue of whether the services were medically reasonable and necessary under the Medicare program in accordance with 42 U.S.C. § 1395y(a)(1)(A). *See* Pl.'s Mem. Summ. J. at Exs. A, B, C. These prior ALJ decisions exclusively addressed the coding issue and did not examine or evaluate the medical necessity issue. *Id.* As such, Plaintiff cannot meet the second element for collateral estoppel. *See, e.g., Sartin v. Macik*, 535 F.3d 284, 287-92 (4th Cir. 2008) (holding that default judgment against debtor did not have collateral estoppel effect because it did not satisfy the "actual litigation" element); *Uzdavines v. Weeks Marine, Inc.*, 418 F.3d 138, 146 (2d Cir. 2005) (holding that fact established in prior litigation by stipulation has not been "actually litigated"); *In re Raynor*, 922 F.2d 1146, 1149-1150 (4th Cir. 1991) (holding that state court proceeding did

not have collateral estoppel effect because the issue of fraud was not actually litigated where debtor was not aware of the prior proceeding, the trial record documented no cross examination of the other party's witnesses took place, and debtor bore the burden of showing a defense to fraud); *Cal. Cmty. Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it "need not address" the issue); *see also Interoceanica v. Sound Pilots*, 107 F.3d 86, 91-92 (2d Cir. 1997) (finding issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *Donovan v. Fed. Clearing Die Casting Co.*, 695 F.2d 1020, 1022 (7th Cir. 1982) (issue not actually litigated when issue left expressly undecided by decision).

3. *The Secretary was not fully represented in the prior actions.*

Finally, the fifth element is not met because the Secretary's opportunity to litigate is limited in Medicare coverage appeals. He cannot participate in the first two levels of the administrative appeal process. *See* 42 C.F.R. §§ 405.948 (Conduct of Redetermination), 405.968 (Conduct of Reconsideration); *see also Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 182 (D.D.C. 2011) ("[I]f a [Medicare contractor] finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the [Medicare contractor's] decision nor opportunity to review those actions.").

The Secretary's participation is also limited in ALJ appeals. Unless the request for hearing is filed by an unrepresented beneficiary, CMS or one of its contractors may elect to be a party to the hearing. 42 C.F.R. § 405.1012(a)(1). Although the Secretary *may* participate or become a party in ALJ hearings, it is impracticable for the Secretary to litigate over 400,000

Medicare claims appeals filed each year at the ALJ level.<sup>13</sup> 42 C.F.R. §§ 405.1010(a), 405.1012; *see also* U.S. Gov. Accountability Office Report at 1, 12 (May 2016), *available at* <https://www.gao.gov/assets/680/677034.pdf> (last visited July 18, 2022); 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016). If the Secretary does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing to have the right to appeal any decisions favorable to the provider or beneficiary.

Furthermore, neither CMS nor the Medicare contractor was a party to any of these ALJ decisions Vein & Wellness claim operate to bind the Secretary. All three ALJ decisions unequivocally state that while Vein & Wellness was represented by counsel during the proceeding, “[n]o other parties appeared for the hearing.” *See* Pl.’s Mem. Summ. J. Ex. A at 2, Ex. B at 3, Ex. C at 3. Accordingly, the Secretary was not fully represented in these prior ALJ proceedings because no one was representing the Secretary’s interests on the issue of whether the MOCA procedures were medically reasonable and necessary under the Medicare program. Under Maryland law, “the analysis of privity for purposes of collateral estoppel focuses on whether the interests of the party against whom estoppel is sought were fully represented, with the same incentives, by another party in the prior matter.” *Mathews v. Cassidy Turley Maryland, Inc.*, 80 A.3d 269, 294 (Md. 2013).

Here, the Secretary and the ALJ who decided these three previous administrative cases at

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<sup>13</sup> The Medicare program handles 1.2 billion Medicare claims per year and covers over 60 million Americans. *See* “What is a MAC?,” *available at* <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC> (last visited July 18, 2022); “Medicare Enrollment Dashboard,” *available at* <https://www.cms.gov/Research-Statistics-Data-and-Enrollment/Enrollment%20Dashboard.html> (last visited July 18, 2022).

Exs. A, B, and C to Plaintiff's Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment and in Support of Plaintiff's Cross-Motion for Summary Judgment are neither the same party nor in privity with one another because they operate pursuant to completely different statutory purposes, power, and interests. *See United States v. Alky Enterprises, Inc.*, 969 F.2d 1309, 1314-15 (1st Cir. 1992) (holding that Interstate Commerce Commission was not in privity with U.S. Attorney General for preclusion purposes because the former "did not have the statutory authority to represent" the interests of the latter). The ALJ does not represent the interests of the Secretary. "Medicare Program: Changes to the Medicare Claims Appeal Procedures; Interim Final Rule," 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) (explaining the ALJ's role as an independent evaluator of the facts who must correctly apply the applicable law); *see also Prosser*, 2020 WL 3642315, at \*7 ("The ALJ is the Secretary's assigned adjudicator, not his representative."). For example, ALJ's are specifically authorized to decline to follow agency policies in a particular case so long as he/she explains the reason why the policy was not followed. 70 Fed. Reg. at 11458.

In sum, the record shows the Secretary did not have a full and fair opportunity to litigate the issue of whether the MOCA procedure was medically reasonable and necessary under Medicare at the time the services were performed. The Secretary cannot be bound by an ALJ decision issued as part of a proceeding where the Secretary's interests were not adequately represented. *See, e.g., Taylor v. Sturgell*, 533 U.S. 880, 892-96 (2008) (holding that a party has had a full and fair opportunity to litigate an issue only if she was a party in the prior suit, with certain limited exceptions not applicable here); *Nationwide Mut. Ins. Co. v. Welker*, 792 F. Supp. 433, 436 (D. Md. 1992) (holding that state court tort action did not collaterally estop declaratory judgment action where the insurance company was not a party to the state negligence litigation,

nor were its interests represented there).

4. *The lack of incentive to litigate the ALJ decisions weighs against preclusion.*

Courts have also recognized an exception to applying preclusion even where all the elements for estoppel are met. Where there is an incentive against extensively litigating smaller matters (because cost outweighs the size of the issue), it is unfair to allow the decisions in those smaller matters to have large preclusive effects. Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and nonprecedential ALJ decisions should not be given preclusive effect, which would result in great cost to the Medicare Trust. *See Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019) (holding that the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present").

**IV. Conclusion.**

It is undisputed that the Secretary's final administrative decision is both legally correct and supported by substantial evidence. As a result, the decision should be upheld affirming the determination of the overpayment against the Plaintiff.

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Respectfully submitted,

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